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The Feasibility of Gathering Patient-Reported Outcome Measures on Individuals with Acute Ankle Sprains in a Busy Clinic Environment

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Abstract

Ankle sprains are the most common sports injury and can lead to long-term deficits. Patient-reported outcome measures (PROMs) may assist clinicians in evaluating the recovery trajectory of patients with ankle sprains. However, before a large-scale study can be performed, it is necessary to determine whether it is feasible to collect PROMs in a busy clinic environment. This study had a narrow recruitment window but the consent rate was 100%. Ten patients at Fowler Kennedy Sport Medicine Clinic were followed for up to six visits. Three PROMs that characterized lower extremity function were measured. The measurement completion rate decreased from 100% at Visit 1 to 40% at Visit 6. The retention rate was 40% and adherence was 76.7%. The data from these participants indicates that there appear to be strong relationships between the PROM scores. The findings from this feasibility study can assist researchers conducting future investigations using similar methodology.

Keywords

Ankle sprain, patient-reported outcome measures, LEFS, FAAM, FADI, feasibility, recruitment, measurement completion rate, retention rate, adherence

Lay Summary

Ankle sprains are the most common sports injury and can lead to long-term issues. Patient-reported outcome measures (PROMs) may assist clinicians in evaluating the recovery path of patients with ankle sprains. However, before a large-scale study can be performed, it is necessary to determine whether it is possible to collect PROMs in a busy clinic environment. Recruitment for this study took place over a two-month period. All eligible patients who were approached agreed to participate in the study. Ten patients at Fowler Kennedy Sport Medicine Clinic enrolled in the study and were followed for up to six visits. Three PROMs that characterized lower extremity function were measured. All ten participants completed each of the three PROMs during their initial visit (measurement completion rate = 100% at Visit 1). This value dropped to 40% by the sixth visit. Four of the 10 participants remained in the study for its entirety (retention rate = 40%). The ten participants attended a total of 46 out of the maximum 60 visits (adherence = 76.7%). The data from these participants indicates that there appear to be strong relationships between the PROM scores. The findings from this feasibility study can assist researchers conducting future work using similar methods.

Co-Authorship Statement

This study was designed in collaboration with Greg Alcock MScPT, Dr. Kevin Willits, and Dr. Jim Dickey. I was responsible for writing the ethics application. I worked with Greg Alcock and the staff at Ortech Systems Inc. to create the study database. I was responsible for recruiting eligible patients and conducting all data collection procedures. I wrote the original draft of this thesis and Greg Alcock and Dr. Jim Dickey provided me with suggestions and comments to improve the final thesis submission.

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Chapter 1

1 Introduction

Ankle sprains are the most common injury amongst athletes and a significant proportion of those individuals experience less than ideal outcomes (Fong et al., 2007; Kaminski et al., 2013). For example, individuals who experience a sprained ankle are at an elevated risk of experiencing recurrent sprains, prolonged symptoms, a higher susceptibility to developing chronic ankle instability (CAI), and an increased risk for post-traumatic ankle osteoarthritis (Beynnon et al., 2002). CAI is characterized by feelings of giving way and instability, recurrent sprains, weakness, pain during activity, and self-reported disability (Delahunt et al., 2010). It is reported that 20% of individuals with acute ankle sprains develop CAI (Chan et al., 2011).

There are two domains of CAI: mechanical instability and functional instability (Tropp, 2002). They can present independently or in combination to give the clinical presentation of CAI. Mechanical instability is defined as movement of the ankle that is beyond the physiologic limit of the ankle's range of motion (Tropp, 2002). This is the most common scenario and patients are typically asymptomatic and do not require treatment. Functional instability is defined as the subjective feeling of ankle instability or recurrent symptomatic ankle sprains due to neuromuscular and proprioceptive deficits (Tropp, 2002). The vast majority of ankle sprains can be treated conservatively, no matter what combination of these domains may be present. A previous study indicated that nearly two-thirds of athletes who reported CAI did not indicate a prior ankle sprain on their assessment survey (Tanen et al., 2014). This demonstrates the ambiguity in defining CAI and helps to explain why quantifying cases of CAI in the literature presents a unique challenge due to the variety of symptoms and characteristics that could be used to describe this condition (Herzog et al., 2019). The gold standard definition of CAI would involve a combination of mechanical and functional instability that repeatedly failed through attempts at conservative management. The gold standard definition of CAI is rare and may require orthopaedic surgical intervention.

Although most athletes return to activity within six weeks of an ankle sprain, almost three-quarters report residual symptoms such as pain, loss of function, perceived instability, weakness, and repeated injury (Anandacoomarasamy & Barnsley, 2005; Braun, 1999). A recent review paper determined that 5% to 33% of patients still experience pain one year following an ankle sprain and the risk of re-sprain ranged from 3% to 34% of patients (van Rijn et al., 2008). Further, the majority of athletes (74%) reported at least one residual symptom up to four years following their injury (Anandacoomarasamy & Barnsley, 2005).

As ankle sprains commonly affect athletes, it is important to examine the potential impact this injury could have to a sports team. In the United States, ankle sprains are the most prevalent injury in the high school and college athletic population, accounting for 23% and 15% of injuries respectively (Hootman et al., 2007; Nelson et al., 2007; Swenson et al., 2009; Waterman et al., 2010). A similar rate of ankle injury in high school athletes has also been documented in Canada (Emery et al., 2007).

Ankle sprains also affect professional athletes, especially in sports such as volleyball, football, basketball, ice hockey, and soccer (Fong et al., 2007). For example, in basketball ankle sprains account for 45% of sustained injuries and 53.7% of the total time missed from competition (Trevino et al., 1994; McKay et al., 2001). Steph Curry is likely the most notable basketball athlete to have a long-troubled history of ankle sprains. An athlete that all sports fans are familiar with, Steph Curry is a star player in the National Basketball Association (NBA) and one of the best three-point shooters of all time. His play and leadership has helped the Golden State Warriors win three of the past five NBA Championships. Curry's problems started back in the 2010-11 season when he injured his ankle multiple times, forcing him to undergo offseason surgery to repair torn ligaments. In the following lockout-shortened season, Curry re-injured his ankle on three occasions, only playing in 26 of a possible 66 games. He underwent an additional surgery to remove loose debris and clean out scar tissue. In the 2015-16 season, following three years of relative good health, Curry once again aggravated his ankle injury, this time in the first round of the playoffs and missed the following two games. Most recently, in the 2017-18 season, Curry sprained his ankle four times and only played in 51 of 82 regular season

games. Over the course of Curry's career, his missed games due to ankle injuries have cost the Golden State Warriors approximately \$15.5 million in player salary. Steph Curry has had a successful ten-year career thus far, however, ankle sprains have prevented him from playing in a significant number of games (Fox Sports, 2018). This example illustrates that a recurrent ankle issue to a star player could change a team's entire season outcome. Therefore, ankle sprains can impact a team's success by causing athletes to miss significant playing time and also by potentially impacting their performance levels upon their return from injury. Additionally, there is the potential for significant financial ramifications to the organization in the case of an ankle injury to a professional athlete.

Ankle sprains place financial burden on the healthcare system. Although Canadian figures are not available, in the United States the average cost to the healthcare system is approximately \$1000 for every individual that reports to the emergency department with an acute ankle sprain (Shah et al., 2016). This excludes the cost of additional care such as physiotherapy, lost work time, and in some cases advanced imaging or surgery. It is reported that 25% of individuals who sprain their ankle are unable to attend school or work for a period greater than seven days following their injury (de Bie et al., 1997). An estimated 28000 ankle injuries occur in the United States each day (Adams et al., 2008). This would equate to over ten million ankle injuries per year. Accordingly, it is estimated that \$10 billion dollars is spent annually on the treatment of ankle sprains in the United States (Adams et al., 2008; Knowles et al., 2007; Shah et al., 2016; Waterman et al., 2010). To reduce these costs, it is important to identify the subset of ankle sprains that do not fully recover. According to a review paper, 15% to 64% of patients do not report a full recovery within three years following their sprain (van Rijn et al., 2008). This illustrates that a significant percentage of individuals still experience residual symptoms even years following an ankle sprain. Although it is unrealistic to expect that all ankle sprains will achieve full recovery, it may be possible to reduce the proportion of individuals who experience residual symptoms and develop CAI.

It would appear that the assessment and management of ankle sprains has room for improvement. Through identifying the individuals with ankle sprains that are not recovering as expected, clinicians may alter their treatment plan which may lead to

streamlined care and potentially decrease healthcare costs.

An example of this can be illustrated through a case study that was examined by the student investigator and clinician co-investigator of this study. A patient reported to Fowler Kennedy Sport Medicine Clinic following an ankle injury sustained playing soccer. The patient was diagnosed with an ankle sprain and was treated conservatively for a period of five months. During this time, the patient was not improving and a series of expensive medical imaging tests were ordered including stress-view x-rays, CT scan, and MRI. At four weeks' time, the patient's history, clinical exam, and self-report measures identified that it would be appropriate to consult an orthopaedic surgeon. However, it was not until five months following the injury that the patient received an orthopaedic consultation where it was confirmed that her injury required surgical intervention. In total, after the surgery, the cost of treating this patient was over \$9,900, with additional costs for physiotherapy appointments that were required for months following the surgery and the patient's lost income as a result of being unable to work for several months. There was the potential of significant cost savings in terms of medical imaging and clinical visits if the patient's lack of response to conservative treatment was identified earlier. Additionally, the patient may have reached full recovery and been able to resume working at an earlier date. In this case, the patient's mechanism of injury, clinical presentation, and self-report measures identified that the patient was not responding to conservative management. The information provided by self-report measures might have assisted clinicians to identify that this individual was failing to progress as expected, earlier in the care delivery process.

The traditional model of clinical assessment for ankle sprains includes taking a medical history, physical examination, special tests, and possible x-rays or advanced imaging. The subjective history and mechanism of injury reported by the patient are of utmost importance as they typically guide the usage of clinical special tests and requests for medical imaging. By combining physical observation and palpation with the patient's history and the mechanism of injury, the clinician gains insight towards the anatomical structures that may have been injured during an ankle sprain. This is typically followed by an assessment of the active, passive, and resisted range of motion of the ankle to

determine which structures may be involved. If a ligamentous injury is suspected following an ankle sprain, then clinical special tests such as the anterior drawer test can be performed to determine if there is laxity in the ankle ligaments of the affected side compared to the contralateral side (Kaminski et al., 2013). Clinical special tests tend to have better diagnostic accuracy when performed directly after injury and before joint effusion has accumulated (Kaminski et al., 2013). However, these special tests often have poor sensitivity and specificity. For example, the sensitivity values for the anterior drawer test have been reported to range from 32% to 80% (van Dijk & Lim et al., 1996; Blanshard et al., 1986; Raatikainen et al., 1992), with a specificity of 80% (van Dijk & Lim et al., 1996; van Dijk & Mol et al., 1996). Based on the limitations of these tests, there is a need for a novel approach to assess ankle sprains.

Patient-reported outcome measures (PROMs) are tools used by clinicians to assess the effect of treatment interventions (Martin & Irrgang, 2007). They have become increasingly popular as they are quick to complete and provide scores that may be clinically meaningful (Eechaute et al., 2007; Martin & Irrgang, 2007). The patient's perspective has become more recognized in healthcare as it is argued to be the most important criterion for judging the effectiveness of the treatment (Parker et al., 2003). PROMs may be helpful in discriminating between different recovery trajectories to determine which sprains are likely to reach a successful endpoint and which sprains will require additional care. A recent review paper suggests that the patient perceptions provided by PROMs may reveal characteristics that are specific to the individuals' impairment which may help guide rehabilitation and may improve the quality of care that clinicians provide (Houston et al., 2015).

PROMs have not been included in the traditional model of clinical assessment due to concerns over clinicians being unable to select the correct instrument to be used and properly interpret the scores that are generated (Martin & Irrgang, 2007). Factors that influence the incorporation of PROMs into clinical assessment include the psychometric evidence available to support score interpretation and the characteristics of subjects included in the studies that offer this evidence (Eechaute et al., 2007; Martin & Irrgang, 2007).

There are four types of PROMs: generic, disease-specific, region-specific, and patient-specific (Martin & Irrgang, 2007). In a clinical setting where ankle sprain outcomes are assessed, it is more practical to use region-specific instruments that have evidence to support their use among subjects with different conditions e.g. inversion ankle sprain versus a high-ankle sprain (Martin & Irrgang, 2007). Prime examples of these instruments that can be applied to ankle sprains include the Lower Extremity Functional Scale (LEFS), the Foot and Ankle Ability Measure (FAAM), and the Foot and Ankle Disability Index (FADI). These three PROMs are all classified as region-specific outcome measures. In addition to supervised rehabilitation, neuromuscular retraining, and activity specific functional testing, it has been recommended that clinicians monitor patient progress using region-specific outcome measures to ensure complete recovery following injury (Houston et al., 2015).

The LEFS is a broad region-specific tool that is used clinically to assess conditions pertaining to the entire lower extremity. The FAAM and FADI are region-specific measures which solely assess conditions relating to the foot and ankle joints. There would be great value in clinicians using fewer tools to aid in the assessment of ankle sprains while still maximizing the amount of meaningful information being collected. Clinicians assess patients with a wide range of injuries, therefore it would be beneficial from an efficiency and simplicity standpoint for them to use one region-specific measure for all cases related to the entire lower extremity. This would save clinicians from having to use the various joint or disease-specific measures that exist for lower extremity conditions.

Sports medicine clinics are busy environments with a steady flow of patients and a wide range of patient exercises and procedures taking place. Clinicians have a plan in place for every patient that they assess and treat. Any deviation to this plan can result in increased appointment times and a resulting increased wait time for subsequent patients. Since many PROMs including the FAAM and FADI are not incorporated into the traditional management model for ankle sprains, it is important to determine whether these PROMs can be collected as part of a research project without disrupting patient flow. This motivated us to evaluate a widely used outcome measure that pertains to the entire lower extremity, the LEFS, and compare it to joint-specific outcome measures that are not

typically incorporated in the assessment of ankle sprains, the FAAM and FADI.

Aside from disrupting clinic flow, it is also important to determine if a full-scale study can be successfully conducted from a research perspective. Not being able to recruit enough participants and poor retention rates are potential challenges. These are two additional reasons why a feasibility study is necessary. This feasibility study will focus on the five main feasibility objectives described by Orsmond and Cohn (2015): (a) evaluation of recruitment capability and resulting sample characteristics, (b) evaluation and refinement of data collection procedures and outcome measures, (c) evaluation of acceptability and suitability of study procedures, (d) evaluation of resources and ability to manage and implement the study, and (e) preliminary evaluation of the results. These objectives will highlight elements such as recruitment and consent rates, measurement completion rates, retention rates, loss-to-follow-up, and adherence. This study will explore the feasibility of gathering the LEFS, FAAM, and FADI on individuals with an acute ankle sprain for up to six visits in a busy clinic environment. This feasibility study will provide insight prior to engaging in a full-scale study focused on the quantitative evaluation of the relationships between the LEFS, FAAM, and FADI.

Chapter 2

2 Methodology

This feasibility study was performed according to the guidelines presented in Orsmond and Cohn (2015). A sample of patients with ankle sprains that present at Fowler Kennedy Sport Medicine Clinic – 3M Site (FKSMC – 3M) was followed to evaluate aspects related to the feasibility of conducting a fully powered study evaluating their recovery trajectory.

2.1 Institutional Approval

Ethics approval was obtained from the Western University Health Sciences Research Ethics Board (HSREB protocol number 112564).

2.2 Eligibility Requirements

Patients were eligible to participate in this study if they were a patient at FKSMC – 3M, were 16 years of age or older, and were provided with a physiotherapy referral for an acute ankle sprain.

Potential participants were excluded from participating in this study if they were under 16 years of age, were unable to read and understand English, or were unable to have their physiotherapy at FKSMC – 3M. Additionally, potential participants were excluded if they had previous foot or ankle surgery, had sustained any other lower extremity injury that would alter self-report scores (e.g. recent knee surgery), or had any other systemic or neuromuscular diseases that would affect self-report scores. Lastly, potential participants were also excluded if their ankle injury required surgical intervention.

2.3 Participants

The participants included ten young, active individuals (six females, four males) residing in London, Ontario. The participants ranged in age from 16-21 (Mean age = 18.8). Nine of the participants were university students and one was a high school student. All

patients had sustained an acute ankle sprain and were first assessed in the clinic within fourteen days of their injury.

2.4 Recruitment Procedures and Consent Process

To assist in recruitment, the research team informed the clinicians and student Varsity team trainers, who may have access to patients with acute ankle sprains, about the study. The student investigator gave a presentation about the research study during orthopaedic research rounds to the staff at FKSMC – 3M. The student investigator also spoke to the student trainers of the Western University Varsity sports teams to inform them about the study. Additionally, the clinician co-investigator discussed the study in detail with the primary care physicians and physiotherapists who covered the acute injuries clinic at FKSMC – 3M.

All participants were recruited from FKSMC – 3M. Initial contact was made by the clinician co-investigator. The clinician co-investigator diagnosed the potential participants' ankle sprain. The clinician co-investigator ensured that the potential participants satisfied the inclusion criteria. Following the diagnosis, the clinician co-investigator described the research study to the potential participants. The co-investigator then asked the potential participants if the student investigator could approach them with further information about the study. Upon receiving patient approval, the student investigator spoke to the potential participants in person, provided them with the Letter of Information, and answered their questions. If the potential participants were interested in joining the study, the student investigator obtained their written informed consent.

2.5 Measures

The FAAM and FADI were collected solely for research purposes. The LEFS is collected as part of the standard of care for conditions affecting the lower extremity but was used for research purposes in this study. All three of these PROMs were collected during each of the participants' visits to the clinic using an iPad tablet.

The FAAM is a region-specific PROM designed to assess physical function for individuals with foot and ankle related impairments (Martin et al., 2005). This instrument

contains two subscales; the Activities of Daily Living (ADL) Subscale and the Sports Subscale. Answers for questions on both scales are based on a Likert-like scale ranging from zero (“unable to do”) to four (“no difficulty”) (Martin et al., 2005). If the activity mentioned in the question is limited by something other than their ankle, the patient is instructed to select “N/A”; these questions are not counted. The scores for each of the questions are added together to get the total score of the subscale. The total number of answered questions is multiplied by four to get the highest potential score. For the ADL subscale, if all 21 questions were answered, the highest potential score is 84. If one question is unanswered the highest total score is 80, if two are unanswered the total highest score is 76. The total score of the subscale is divided by the highest potential score and is then multiplied by 100 to generate the ADL score which ranges from 0 to 100. The Sports subscale is scored similarly. If all seven questions are answered, the highest potential score is 28. As with the ADL subscale, the total score is divided by the highest potential score and multiplied by 100. For both the ADL subscale and Sports subscale, a higher score indicates a higher level of physical function (Martin et al., 2005). For the purpose of this study, the FAAM ADL Subscale will be abbreviated as “FAAM ADL” and the FAAM Sports Subscale will be abbreviated as “FAAM Sports”. In each subscale, the patient also reports their current level of functioning during their typical activities of daily living and during their sports related activities from zero (unable to perform usual activities) to 100 (patient’s prior level of function) (Martin et al., 2005). Additionally, the patient is also asked to rate their current level of function as “normal”, “nearly normal”, “abnormal”, or “severely abnormal”. The FAAM is a reliable, responsive, and valid measure of physical function for individuals with musculoskeletal disorders of the foot and ankle (Martin et al., 2005). The FAAM is able to distinguish between individuals with healthy ankles and individuals with CAI (Carcia et al., 2008; Martin et al., 2009). Compared to healthy controls, individuals with CAI report decreased ankle function for both the ADL and Sports Subscales (Houston et al., 2015).

The FADI is a region-specific PROM designed to assess functional limitations related to foot and ankle conditions (Martin et al., 1999). The FADI assesses activities of daily living and pain and consists of 26 items. The domains covered by this outcome measure are activities of daily living and pain. Each ADL item is scored on a Likert-like scale

from zero (“unable to do”) to four (“no difficulty at all”). The four pain items of the FADI are scored zero (“unbearable”) to four (“no pain”). In addition, there is a Sports Subscale of the FADI consisting of eight items which is scored in the same manner on a Likert Scale from zero (“unable to do”) to four (“no difficulty at all”). The FADI has a total point value of 104 points whereas the Sports Subscale has a total point value of 32. For both, a higher score reflects a higher level of physical function (Hale & Hertel, 2005). For the purpose of this study, the score generated from the questions pertaining to activities of daily living and pain will be abbreviated as “FADI ADL” and the score from FADI Sports Subscale will be abbreviated as “FADI Sports”. Both Subscales of the FADI are responsive to improvements in function after rehabilitation and prior research advocates for its use in clinical care and research applications in young adults with CAI (Hale & Hertel, 2005). Similar to the FAAM, patients with CAI report decreased ankle function for both the ADL and Sports Subscales of the FADI (Houston et al., 2015).

The LEFS is a 20-item questionnaire designed to assess the functional status of patients for a wide spectrum of lower extremity conditions (Binkley et al., 1999). The items investigate the degree of difficulty in performing different functional tasks due to the extent of injury in the lower extremity (Cacchio et al., 2010). Each item is scored on a Likert-like scale from zero (“extreme difficulty or unable to perform activity”) to four (“no difficulty”). The scale is scored by tallying the responses for all of the items and has a total possible score of 80. A higher score indicates a higher level of functionality. For the purpose of this study, the score generated will be termed “LEFS Score”. The scale is one page and can be filled out by most patients in less than two minutes. The LEFS can be used to evaluate injuries to the entire lower extremity and is efficient to administer and score. Additionally, the LEFS is sensitive to changes in patients’ functionality and is therefore applicable for research purposes and clinical decision making for individual patients (Binkley et al., 1999).

Each participant provided a list of personal identifiers during their initial research visit. These personal identifiers included full name, initials, full date of birth, age, and sex. Additional demographic characteristics that were collected included level of education, level of athletic involvement, principal diagnosis, and injured side.

To help determine whether it is feasible to collect these PROMs in a busy clinic environment, several elements of feasibility were evaluated and are presented in Table 1.

Table 1: Elements of Feasibility that were Evaluated and Their Related Feasibility Objective

Feasibility Element	Definition of Feasibility Element	Related Feasibility Objective
Recruitment rate	The number of individuals recruited from those interested (Brooker et al., 2019)	Evaluation of recruitment capability and resulting sample characteristics
Consent rate	The percentage of individuals who consented to be involved in the study, of those deemed eligible (Brooker et al., 2019)	Evaluation of recruitment capability and resulting sample characteristics
Measurement completion rate	The number of participants who were able to complete each PROM divided by the total number of participants (Brooker et al., 2019); calculated at each of the six time points	Evaluation and refinement of data collection procedures and outcome measures
Retention rate	The percentage of participants who remained in the study for its entirety (Brooker et al., 2019)	Evaluation of acceptability and suitability of study procedures
Loss-to-follow-up	Participants who withdrew or dropped out and did not attend a follow-up visit (Brooker et al., 2019)	Evaluation of acceptability and suitability of study procedures
Adherence	Total number of physiotherapy visits attended out of the maximum 60 visits (Brooker et al., 2019)	Evaluation of acceptability and suitability of study procedures

2.6 Procedures

After providing their written informed consent, participants were entered into the study. The student investigator provided the participants with an iPad that they used to collect all necessary data for the measures listed above. All of the data was collected at FKSMC – 3M on an iPad tablet using a proprietary web application for orthopaedic research. The electronic data were stored by Ortech Systems Inc. in their privacy compliant encrypted database, phiDB (<https://phidb.ortechsystems.com/Global/Login>). Ortech Systems Inc. is located in London, Ontario.

The participants were first prompted to enter some personal identifiers. Additional demographic characteristics were also collected at this time. The participants were only required to provide the personal identifiers and demographic characteristics during their initial visit. Following this, the participants completed the three PROMs described in the above section (i.e., the LEFS, FAAM, and FADI). The participants were able to complete the PROMs on the iPad tablet while they received some therapeutic modality such as ice and compression, electronic muscle stimulation, or ultrasound. The participants were assessed for up to six visits and completed the three PROMs during each visit.

2.7 Statistical Analysis

All participants completed the LEFS, FAAM, and FADI during their initial visit. We generated the summary statistics at baseline to represent the mean, standard deviation, and the minimum and maximum values for the LEFS Score, FAAM ADL, FADI ADL, FAAM Sports, and FADI Sports.

We originally intended to perform a cross-sectional analysis to determine the relationships between the PROMs at the three-week visit, however, we were unable to do this as there were incomplete data for this time point. All of the participants attended at least one visit so we compared their baseline scores. These comparisons were depicted on scatter plots to show the relationships that existed between the PROMs.

We were interested in the relationships between the PROMs related to activities of daily living, and to sports related activities. Accordingly, we performed correlations between

the LEFS, FAAM ADL, and the FADI ADL scores, and also between the LEFS, FAAM Sports, and the FADI Sports scores. The magnitudes of the correlations were used to quantify the strength of the relationships.

Chapter 3

3 Results

This is a feasibility study and therefore the focus will be on the five main feasibility objectives and the different elements that they consider. The fifth main feasibility objective, preliminary evaluation of the results, will include statistical analysis of the data that were collected. All findings from the statistical analyses must be interpreted with caution due to the limited sample size of patients that were included in this feasibility study.

3.1 Evaluation of recruitment capability and resulting sample characteristics

Recruitment for this study was constrained by a narrow recruitment window and a limited number of study eligible patients presenting to FKSMC – 3M. At the start of the recruitment period when patient recruitment proved most challenging, there were a total of 14 ankle cases that presented to the acute injuries clinic at FKSMC – 3M over a four-week period. These patients were not assessed by the clinician co-investigator and accordingly could not be recruited. There were two main reasons why these patients were unable to be assessed by the clinician co-investigator. These included four patients choosing to have their physiotherapy completed at other clinics rather than FKSMC – 3M and four patients being assessed by other clinicians at FKSMC – 3M. Other reasons included physiotherapy not being recommended at this time (two patients), the patient having a fracture (two patients), and the patient being below 16 years of age (two patients).

Two elements of feasibility that are important to mention for this particular objective are recruitment rate and consent rate. The recruitment rate could not be calculated for this study as participants were approached by the student investigator if deemed eligible by the clinician co-investigator i.e., it was not a matter of patient interest. All ten of the patients who were approached agreed to participate in the study and provided their informed written consent (consent rate = 100%). The participant demographics are presented in Table 2.

Table 2: Participant Demographics

Demographic Characteristic	Participants (n=10)
Mean age (years) \pm SD	18.8 \pm 1.3
Sex, n (%)	
Female	6 (60%)
Male	4 (40%)
Level of education, n (%)	
Undergraduate degree	9 (90%)
Current varsity athlete, n (%)	6 (60%)
Principal diagnosis, n (%)	
Inversion sprain	9 (90%)
Injured side, n (%)	
Right	7 (70%)

3.2 Evaluation and refinement of data collection procedures and outcome measures

Although all participants did not attend the full six visits, the LEFS, FAAM, and FADI were completed by all participants for every session that they did attend. Participants had few questions regarding the three PROMs and they took approximately five minutes to complete per session. Participants spent an approximate total of 30 minutes on this study if they attended all six visits. The results for the measurement completion rate are presented in Table 3.

Table 3: Measurement Completion Rate for Six Time Points

Visit Number	Number of Participants Present	Measurement Completion Rate (%)
1	10	100
2	9	90
3	8	80
4	8	80
5	7	70
6	4	40

The iPad application was easy to use and there were no technical difficulties experienced by either the student investigator or the participants. The de-identified data were easy to extract and perform a statistical analysis on.

3.3 Evaluation of acceptability and suitability of study procedures

A total of four participants completed data collection for the intended six time points (retention rate = 40%). These four participants' visits took place during six different weeks, over a period ranging from seven to fifteen weeks. None of the participants completed the data collection in six successive weeks. In total six participants were lost to follow-up. This occurred at different time points (Table 4). Reasons for loss-to-follow-up included five participants reaching full recovery and no longer requiring physiotherapy for their ankle sprain (five of six - 83.3%). Full recovery was determined as a joint decision by both the participant and the physiotherapist. In addition, one participant changed their mind about attending physiotherapy (one of six - 16.7%). Lastly, the ten participants attended a total of 46 visits out of the maximum 60 visits (adherence = 76.7%).

All of the participants expressed interest in the study during the consent process. None of the participants complained about the PROMs that they had to complete nor the time commitment that these required.

Table 4: Timing of Complete Visits for Each of the Ten Participants, Ordered from Least to Most Visits

Participant Number	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Total Number of Visits
4	✓						1
6	✓	✓					2
5	✓	✓	✓	✓			4
1	✓	✓	✓	✓	✓		5
7	✓	✓	✓	✓	✓		5
8	✓	✓	✓	✓	✓		5
2	✓	✓	✓	✓	✓	✓	6
3	✓	✓	✓	✓	✓	✓	6
9	✓	✓	✓	✓	✓	✓	6
10	✓	✓	✓	✓	✓	✓	6

3.4 Evaluation of resources and ability to manage and implement the study

All data collection procedures were conducted by the student investigator. The time commitment required for data collection could be managed by the student investigator. The student investigator was able to attend all participant visits; however, it is important to note that this feasibility study only had ten participants. Participant visits did not overlap and this allowed for a single iPad tablet to be used to collect all data without any issues. No additional research team members were required to assist in data collection. FKSMC – 3M had sufficient space for all data collection procedures to be conducted. The clinician co-investigator was available in clinic for support and to help solve any issues encountered with data collection.

3.5 Preliminary evaluation of the results

The summary statistics and the Pearson correlations for the baseline scores provided during each of the participants initial visits are presented in Tables 5 and 6.

Table 5: Summary Statistics at Baseline

Variable	Observations	Mean	Std. Dev.	Minimum	Maximum
LEFS Score	10	43.1	17.11	11	66
FADI Sports	10	9.3	8.38	0	24
FADI ADL	10	64.3	26.39	19	99
FAAM ADL	10	46.9	27.13	2	77
FAAM Sports	10	6	6.62	0	17

Table 6: Pearson Correlations at Baseline

Variables		Correlation (r-value)
LEFS Score	FAAM ADL	0.939
LEFS Score	FADI ADL	0.974
FAAM ADL	FADI ADL	0.974
LEFS Score	FAAM Sports	0.789
LEFS Score	FADI Sports	0.790
FAAM Sports	FADI Sports	0.980

There were strong relationships between the various PROMs at baseline (Figures 1 through 6).

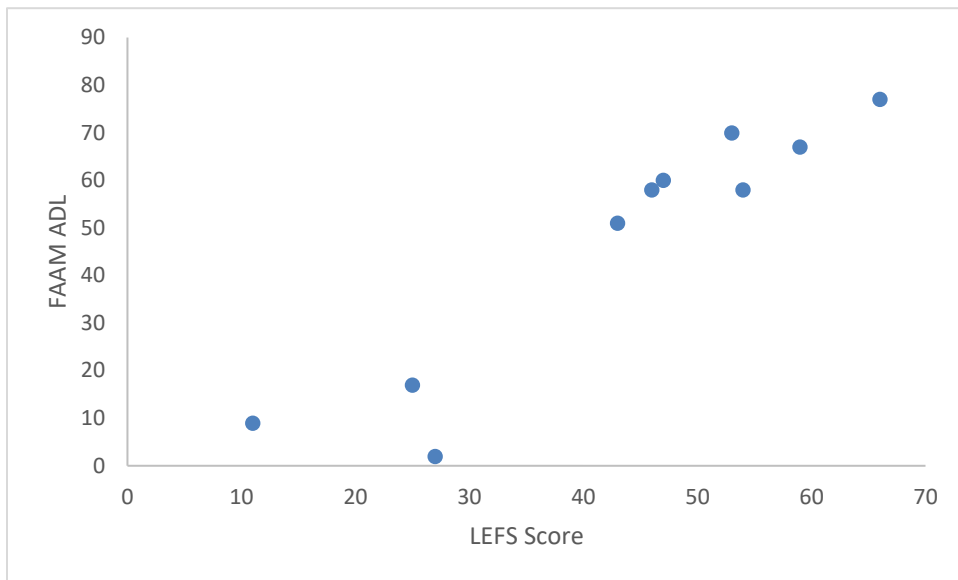


Figure 1: Relationship Between LEFS Score and FAAM ADL for the Ten Participants at Baseline

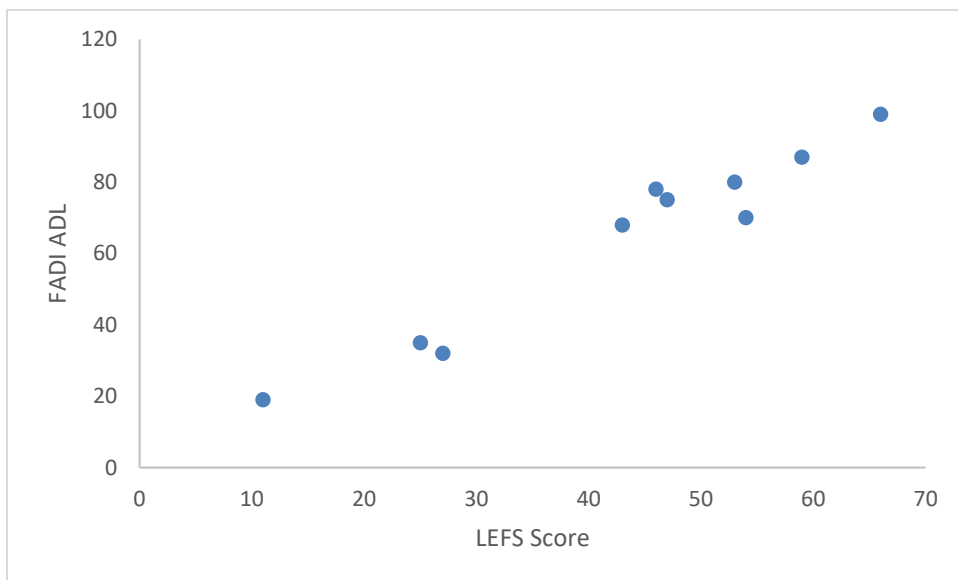


Figure 2: Relationship Between LEFS Score and FADI ADL for the Ten Participants at Baseline

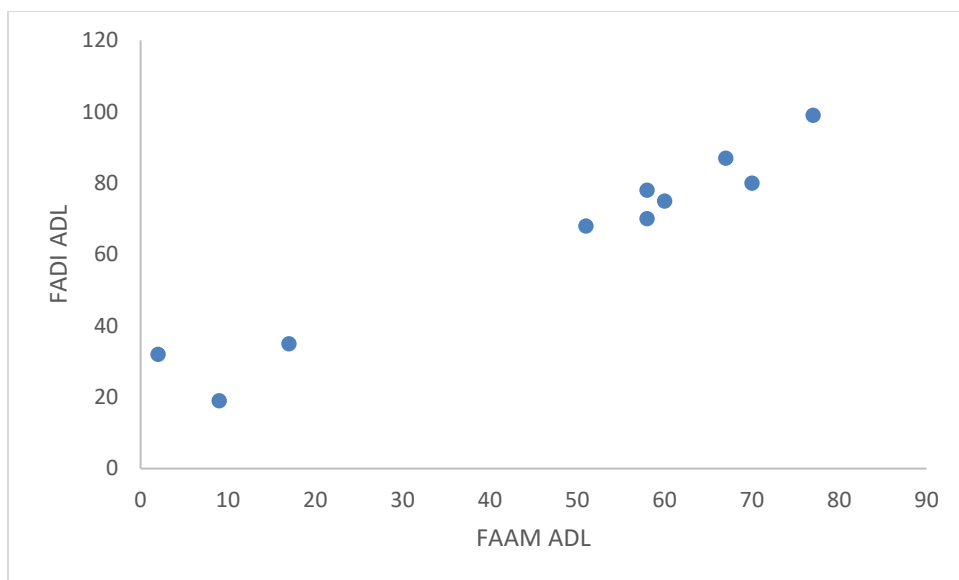


Figure 3: Relationship Between FAAM ADL and FADI ADL for the Ten Participants at Baseline

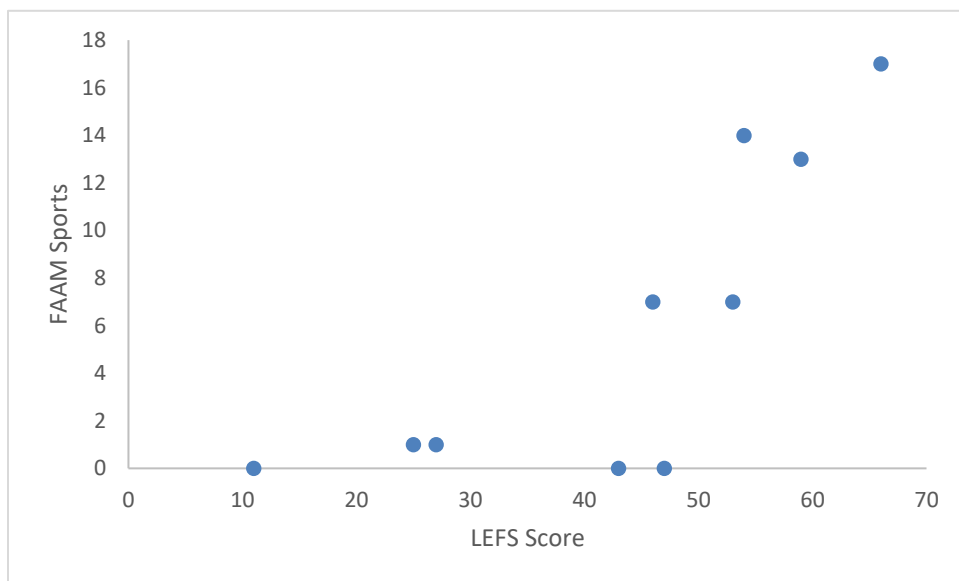


Figure 4: Relationship Between LEFS Score and FAAM Sports for the Ten Participants at Baseline

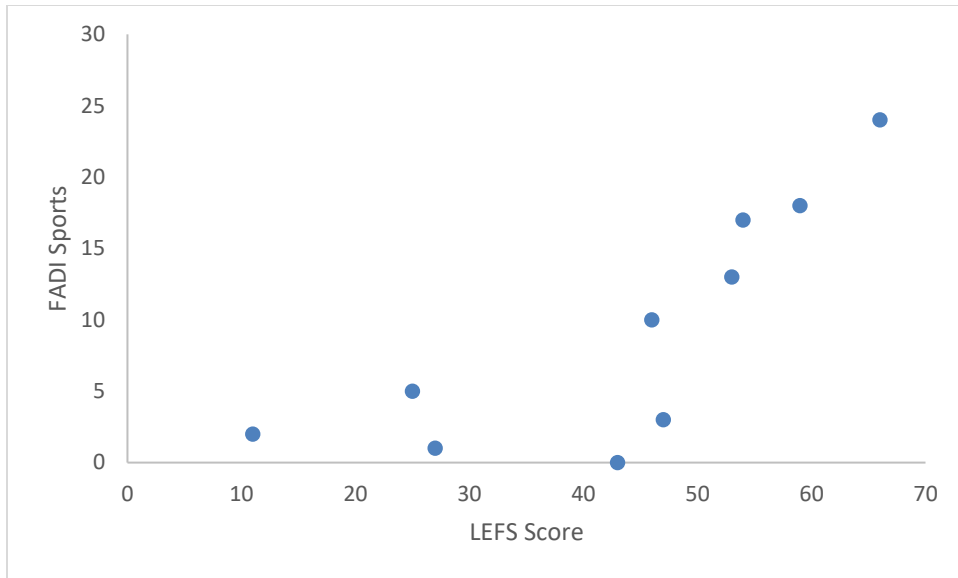


Figure 5: Relationship Between LEFS Score and FADI Sports for the Ten Participants at Baseline

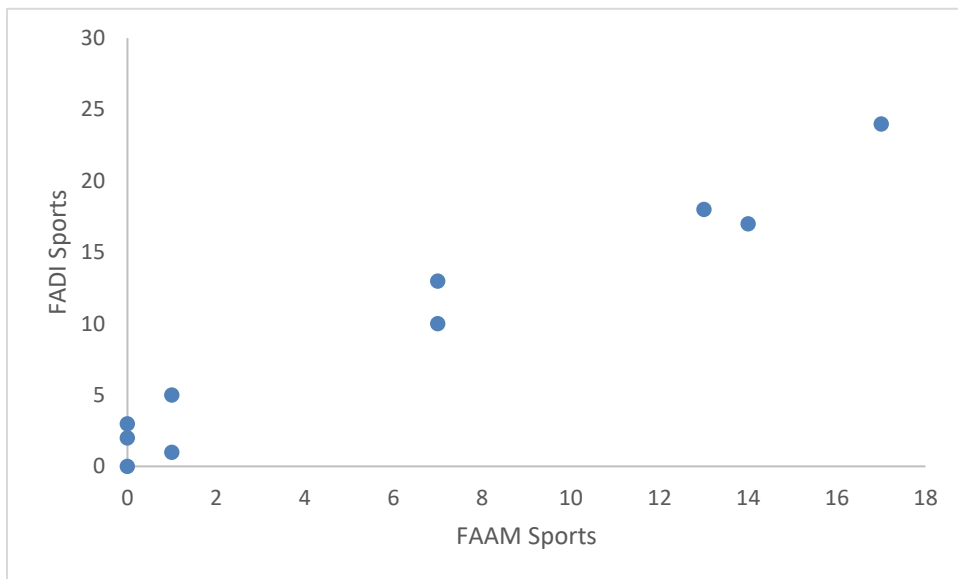


Figure 6: Relationship Between FAAM Sports and FADI Sports for the Ten Participants at Baseline

Chapter 4

4 Discussion

The purpose of this feasibility study was to determine whether the LEFS, FAAM, and FADI measures could be completed by patients with an acute ankle sprain in a busy clinic environment for six visits. For future investigations using similar methodology to be successful, it is essential to use proper recruitment techniques, collect data appropriately, use acceptable outcome measures, have sufficient resources to conduct the study, and generate meaningful information. The five main feasibility objectives stated by Orsmond and Cohn (2015) provide a framework to evaluate important elements pertaining to feasibility.

The first main feasibility objective is the evaluation of recruitment capability and resulting sample characteristics. While reviewing this feasibility objective, it is important to determine if we recruited appropriate participants that are representative of the population of individuals who most commonly sustain ankle sprains (Orsmond & Cohn, 2015). To address this objective, we examined the eligibility criteria, recruitment strategies, feasibility elements including the recruitment and consent rates, and the resulting sample characteristics.

Recruitment for this study was affected by the time constraint of a narrow recruitment window. The narrow recruitment window was the result of two main factors. Firstly, recruitment of participants was delayed by a lengthy research ethics approval process. Secondly, we halted recruitment after a two-month period based on the constraints of the time that was required to collect data balanced against the time that was required to write this thesis.

Another factor affecting patient recruitment was the limited number of study eligible patients who presented to FKSMC – 3M. To be able to successfully recruit study participants, there needs to be a sufficient amount of study eligible patients to approach. One main reason that patients were ineligible was that the patients decided to complete their physiotherapy elsewhere. Although the patients were initially assessed at FKSMC –

3M, they could choose to complete their physiotherapy at another clinic. There is also no guarantee that a patient who chooses to have their physiotherapy at FKSMC – 3M will agree to participate in the study. This stands out as a potential problem for future investigations using similar methodology as both situations decrease the number of potential participants available to be recruited. With fewer eligible participants being available, it is likely that a longer duration of time will be necessary to capture the required number of participants for a fully powered study.

Unfortunately, we were unable to calculate the recruitment rate for this study. Due to the recruitment procedures and consent process of this study, we were unable to determine if patients at FKSMC – 3M were interested in participating in the study. The student investigator only approached patients with further information about the study if they were deemed eligible by the clinician co-investigator. The recruitment strategy for this feasibility study involved informing all student trainers of the Varsity teams at Western University and the primary care physicians and physiotherapists who covered the acute injuries clinic at FKSMC – 3M about the study. Additionally, a presentation about the research study was given during orthopaedic research rounds to the staff at FKSMC – 3M. These were simple yet effective means of informing the key individuals who assisted in recruitment. All of the physiotherapists and primary care physicians assess and treat many patients with a wide range of injuries and there are also numerous research studies being conducted at FKSMC – 3M. The student trainers for the Varsity sports teams typically have a busy schedule between their academics and attending team practices and games. Although the recruitment rate was not calculated for this feasibility study, suggestions can still be made to improve the recruitment process for future investigations using similar methodology. It may be beneficial for the research team leading future investigations to increase the number of presentations to, and conversations with, the primary care physicians, physiotherapists, and student trainers to serve as reminders of the study. Recruitment for this study was also affected by the research ethics approval process taking longer than expected. As a result, we were unable to recruit during Varsity training camps in August and September, a time frame in which many ankle injuries occur. In order to maximize recruitment, it is recommended that researchers leading future investigations target an earlier date for research ethics approval to ensure they have

sufficient time to recruit the required number of participants.

The consent rate for the study was 100% which demonstrates that patients are willing to participate in the study if it is presented to them. Our ten participants were enrolled in the study over a two-month period. There is a realistic possibility that recruiting five patients per month at FKSMC – 3M will remain consistent for future investigations. It is therefore important for the researchers conducting future investigations using similar methodology to plan accordingly and provide themselves with sufficient time to gather the required number of participants for a fully powered study.

The resulting sample characteristics were also an area of interest. Our participants were all young (age in years = 18.8 ± 1.3) and active (60% varsity athletes and all ten participants were involved in sports). Nine participants were university students and the remaining participant was a high school student. Ankle sprains are the most prevalent injury in college and high school athletic populations, accounting for 15% and 23% of injuries respectively (Hootman et al., 2007; Nelson et al., 2007; Swenson et al., 2009; Waterman et al., 2010). The findings from a meta-analysis demonstrated a higher incidence of ankle sprain in adolescents compared with adults (1.94 vs 0.72 per 1,000 exposures) (Doherty et al., 2014). It is also important to note that FKSMC – 3M is located on the main campus of Western University, which is likely contributing to the high percentage of university students amongst our sample. Lastly, 90% of the patients had sustained an inversion sprain to their ankle. This was expected as inversion sprains are the most common type of ankle sprain, representing 85% of ankle sprains (Ferran & Maffulli, 2006; Doherty et al., 2014). The demographics of our sample were expected due to the prominence of ankle sprains in high school and university athletes, the location of the clinic, and the recruitment strategies we used. Although our sample consisted solely of a very specific population, the sample is reflective of the cohort of patients that are treated at FKSMC – 3M for this particular injury.

The second main feasibility objective is the evaluation and refinement of data collection procedures and outcome measures. While reviewing this feasibility objective, it is important to determine the appropriateness of the data collection procedures and

outcomes measures for the intended population and purpose of the study (Orsmond & Cohn, 2015). To address this objective, we examined the measurement completion rate, the ability of patients to complete the PROMs in a timely fashion, and the usability of our data collection platform for both patients and the research team.

From the results, it is apparent that the measurement completion rate declined with each subsequent visit, starting at 100% at “Visit 1” and reaching 40% by “Visit 6”. However, this was due to losing patients to follow-up rather than the measurements not being completed. The positive finding is that all patients completed the PROMs during each visit they attended. This suggests that the outcome measures being collected in this study can be successfully completed by the participants.

The three PROMs consist of a combined total of 85 questions, however, the questions are all completed on a Likert-like scale so they can be answered quickly. The scores generated from these PROMs were easy to interpret as a higher score indicates a higher level of function for all of them (Binkley et al., 1999; Hale & Hertel, 2005; Martin et al., 2005). The study participants completed these PROMs in approximately five minutes per visit. Participants spent a maximum of approximately 30 minutes completing data collection procedures if they attended all six visits. None of the participants voiced any concerns that the time commitment was an inconvenience and they all seemed satisfied that they could complete the PROMs while receiving a therapeutic modality at the clinic. As a result, the length of their physiotherapy visit was not extended as a result of their study participation. The FAAM and FADI were appropriate measures to compare to the LEFS for this study as they are quick and easy to complete and produce clinically meaningful scores that are easy to interpret (Martin & Irrgang, 2007).

All study data were collected electronically on an iPad tablet using a proprietary web application for orthopaedic research. The application was user friendly for both the research team and the participants. The student investigator was able to navigate through the application to get everything ready for the participants and the participants were able to progress through the questions in a timely fashion. There were no technical difficulties experienced by patients or the research team. By collecting all of our study data

electronically on the iPad, there was no need to collate and digitize the data which saved a significant amount of time. The data were secure and when it came time to extract our data, the process was simple to complete. The de-identified data were formatted in a manner that was easy to analyze and could be shared by members of the research team. Additionally, we saved a lot of paper that would be difficult to sort and store. All communication with Ortech representatives was positive and they were prompt to answer any questions that we had. We recommend that Ortech be used as the vendor for data collection for future investigations with similar methodology.

The third main feasibility objective is the evaluation of acceptability and suitability of study procedures. While reviewing this feasibility objective, it is important to determine if the study procedures were suitable for and acceptable to participants (Orsmond & Cohn, 2015). To address this objective, we examined feasibility elements including retention rate, loss-to-follow-up, and adherence.

The retention rate indicates the percentage of participants who remained in the study for its entirety. Only four patients completed six visits of data collection and therefore the retention rate for our study was 40%. This value seems low but the retention rate would have likely been higher had the participants attended their physiotherapy visits in six successive weeks. On average, the four participants who completed all six visits of data collection did so within 8.8 weeks of their initial visit. Regardless, a low retention rate is a possible concern for future investigations using similar methodology. However, it is important to note that our sample only consisted of ten participants and that the retention rate in this sample may not reflect a larger sample size.

Over the duration of the study, six patients were lost-to-follow-up. Five of the six patients were lost-to-follow-up because they had reached a full recovery and no longer required physiotherapy for their ankle sprain. The six patients lost-to-follow-up were lost at different time points with only two patients being lost prior to the fourth visit. Therefore, for future investigations using similar methodology, it is worth considering setting the study endpoint as when a participant is fully recovered.

The patient adherence of 76.7% seems high considering that the retention rate for this

feasibility study was only 40%. The rate of adherence was increased by the fact that three of the participants who were lost-to-follow-up still attended five of the six visits and another participant attended four visits. Adherence is a strong indicator of participants' acceptability of a study's procedures (Brooker et al., 2019). Therefore, despite the low retention rate, the study seemed to be acceptable to the participants.

The fourth main feasibility objective is the evaluation of resources and ability to manage and implement the study. While reviewing this feasibility objective, it is important to determine if the research team had sufficient resources and ability to successfully manage the study (Orsmond & Cohn, 2015). To address this objective, we examined the research team's ability to attend all participant visits and the resources that were available to the research team.

Once a participant was enrolled in the study, the student investigator checked their scheduled appointment times and ensured that he was available to attend the appointment to collect the study data. The student investigator attended all participants' visits and conducted all data collection procedures. The data were collected while the participants were receiving therapeutic modalities at the clinic and this took approximately five minutes per visit. No additional research team members were required to assist in data collection. The clinician co-investigator was available in the clinic to supervise the student investigator and answer any questions pertaining to data collection. The sample size for this study was only ten participants and it is likely that additional research team members would be required to assist in data collection with a larger sample size in future investigations using similar methodology.

In terms of available resources for the research team, a single iPad was all that was required to complete data collection for this study. Participant visits did not overlap with one another so there were no instances where participants had to wait to use the iPad. However, this is a potential issue that may be encountered during future investigations with a larger sample size and additional iPads may be required. FKSMC – 3M is a busy clinic but there was always sufficient space to complete data collection procedures as they were completed while the participants were engaged in treatments so no dedicated

space was required.

The fifth and final main feasibility objective is the preliminary evaluation of the results. While reviewing this feasibility objective, it is important to determine whether the study showed promise of being successful with the intended population (Orsmond & Cohn, 2015). To address this objective, we examined the amount and the usability of the data collected, the early interpretations of the relationships between the PROMs, and what this all means for future investigations using similar methodology. It is recommended that researchers focus on examining the research process in feasibility studies, and wait to examine preliminary efficacy in a study with appropriate design and sample size (Arain et al., 2010).

Although the amount of data collected was limited because of the low retention rate (40%) and measurement completion rate (40% by “Visit 6”), all of the data we gathered were usable. This allowed us to complete our intended comparisons and perform statistical analyses on the data we collected.

Our feasibility study only included a sample size of ten participants. Some researchers argue that conducting inferential statistics and examining effect sizes in feasibility studies is inappropriate with small samples sizes (Dobkin, 2009; Leon et al., 2011). However, the Orsmond and Cohn (2015) framework identifies that it is appropriate to perform preliminary analysis using methods that are applicable to the feasibility study design and outcome measures collected. Therefore, we performed a cross-sectional analysis evaluating the relationships between baseline scores. We correlated the baseline measures of the LEFS Score, the FAAM ADL, and the FADI ADL and then the LEFS Score, FAAM Sports, and the FADI Sports. The relationships between the LEFS, FAAM ADL and the FADI ADL appear to be strong. This is likely the case because all three of these scales ask questions pertaining to functioning in activities of daily living. The relationships between the LEFS, FAAM Sports and FADI Sports are weaker. The weaker relationships are likely due to the LEFS focusing on functioning in normal daily activities while the two Sports Subscales focus on functioning in sports-related activities.

These relationships are worth further exploration. If researchers can determine that the

scores generated from the LEFS can provide the same meaningful information as the scores from the FAAM and FADI, this will allow clinicians to use fewer tools in their management of ankle sprains. This would increase the likelihood of PROMs being incorporated into the management model of ankle sprains. Future investigations using similar methodology with a sample size that is powered for statistical significance will be better equipped to discuss the magnitude of the relationships that exist between the PROMs.

4.1 Limitations

First and foremost, this feasibility study had a sample size of only ten participants. Due to the small amount of data collected and the degree of uncertainty in drawing conclusions, the limited statistical findings are considered to be preliminary (Brooker et al., 2019).

Secondly, participants were not assessed on a weekly basis as originally intended. All data were collected by the student investigator while participants were attending their standard of care physiotherapy visits. Therefore, the scheduling of the participant visits was out of our control. The participants' appointment times were mainly dictated by their injury and its progression, the assessing physiotherapist's recommendations and availability, and the participants' personal schedules. Additional factors that affected participant scheduling included the student winter break and reading week as well as clinic holiday closures. The delays in data collection may have contributed to the low retention rate and participants being lost to follow-up. The longer period of time in between visits increases the likelihood that a patient will be fully recovered and no longer attend physiotherapy.

Thirdly, due to the recruitment process, the recruitment rate could not be calculated for this study. We were unable to quantify the number of interested potential participants as the study's participants were only approached by the student investigator if they were deemed eligible by the clinician co-investigator.

Next, the age range of our study participants was 16 to 21 years of age. The inclusion criteria for our study allows for patients to be eligible if they are 16 years of age and

above. Therefore, our sample reflects a small portion of the potential population that could be included into the study and the results lack generalizability to the rest of the population outside of this narrow age range. However, this age range well-represented the cohort of patients that are treated at FKSMC – 3M.

Additionally, patient recruitment was limited by the research ethics approval process taking longer than expected. This prevented recruitment of participants during Varsity training camps in August and September. It is possible that many potential participants were assessed at FKSMC – 3M during these months.

Furthermore, the Orsmond and Cohn (2015) framework addresses feasibility in the context of intervention research. In contrast, this study explored the feasibility of gathering PROMs in a busy clinic environment. As a result of this not being intervention research, aspects of the five main feasibility objectives described by Orsmond and Cohn were adapted to suit the purpose of this feasibility study.

Moreover, the participants' acceptability of study procedures was not directly assessed in this feasibility study. Therefore, proxy measures, such as the feasibility element of adherence, were used to indirectly measure acceptability.

Lastly, the low measurement completion rate (40% at "Visit 6") and retention rate (40%) limited the amount of data we collected. This could pose potential problems for future investigations that intend to explore the relationships that exist between the LEFS, FAAM, and FADI in patients with an acute ankle sprain.

Chapter 5

5 Conclusion

This study has shown that it is feasible to collect three PROMs on patients with acute ankle sprains in a busy clinic environment without disrupting patient flow but there is room for improvement. Participant recruitment was limited by a narrow recruitment window but all eligible patients who were approached by the research team agreed to participate in the study. The measurement completion and retention rates were both low due to participants being lost to follow-up. The patient adherence was 76.7% and this value reflected the participants' acceptability of study procedures. The feasibility study had sufficient resources and study team members, however, additional resources will be required to complete a larger fully-powered study. We were unable to make strong conclusions regarding the magnitude of the relationships between the PROMs due to the limited sample size available in our feasibility study. However, it appears as if strong relationships exist between the LEFS, FAAM, and FADI. The magnitude of the relationships warrants further investigation to determine if clinicians can use fewer tools in their assessment of acute ankle sprains.

5.1 Future Directions

Future research should be conducted using similar methodology and the recommendations from this feasibility study. Future investigations will require a larger sample size to be adequately powered for statistical significance. This research would be able to address the magnitude of the relationship that exists between the LEFS, FAAM, and FADI. This would allow researchers to determine if the LEFS can track the recovery of patients with ankle sprains to the same extent as the FAAM and FADI. If the LEFS provides clinicians with the same amount of meaningful information as the two other PROMs, then this would allow clinicians to use fewer tools and would increase the likelihood of PROMs being incorporated into the management model of ankle sprains. Additionally, this would establish a connection between the LEFS and other academic literature using the FAAM and FADI which could be investigated further.

Future research should attempt to explore the relationships that exist between the LEFS, FAAM, and FADI measures in patient ankle sprain sub groups. These sub groups may be based on specific pathological sequelae, treatment approaches, or lower extremity alignment variations. This may influence the role and clinician usage of PROMs in assessing a patient's recovery in their rehabilitation. This may inform clinicians on how to incorporate PROMs in their assessment of patients and assist in clinical reasoning.

Future research should investigate if the LEFS, FAAM, or FADI can be used to predict how long it will take for patients to be fully recovered based on baseline scores. Using PROMs to form a predictive individualized model would further aid clinicians in identifying when a patient is not improving from conservative management and may require advanced care such as surgical intervention.

Future research may also explore the relationships between the LEFS and other outcome measures that relate to the patient experience of suffering an acute ankle sprain. The domain of pain throughout the recovery process is significant as is functional performance of sport specific tasks and return to sport testing batteries. Different outcome measures cover other domains relating to the patient experience. Potential examples of outcome measures that could be compared to the LEFS include the Foot and Ankle Outcome Score (FAOS) and the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle Score. The FAOS covers six domains including symptoms, stiffness, pain, function in daily living, function in sports-related activities, and quality of life. In contrast, the AOFAS Ankle Score covers three domains including pain, function, and alignment. Through investigating the relationships between additional PROMs, researchers can more confidently recommend whether clinicians can use fewer tools in their management of ankle sprains. This may provide clinicians with a more simple and efficient approach to assessing ankle sprains and may provide useful information for updating the traditional management model for ankle sprains.

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Appendices

Appendix A: Western Research Ethics Approval



Date: 28 September 2018

To: Dr. Jim Dickey

Project ID: 112564

Study Title: A Comparison of Clinical and Research Based Outcome Measures on Individuals with Acute Ankle Sprains

Application Type: HSREB Initial Application

Review Type: Delegated

Full Board Reporting Date: 02Oct2018

Date Approval Issued: 28/Sep/2018 14:55

REB Approval Expiry Date: 28/Sep/2019

Dear Dr. Jim Dickey

The Western University Health Science Research Ethics Board (HSREB) has reviewed and approved the above mentioned study as described in the WREM application form, as of the HSREB Initial Approval Date noted above. This research study is to be conducted by the investigator noted above. All other required institutional approvals must also be obtained prior to the conduct of the study.

Documents Approved:

Document Name	Document Type	Document Date	Document Version
Ankle Outcome Measures Study Protocol	Protocol	27/Sep/2018	1
Foot and Ankle Ability Measure	Online Survey	01/Nov/2005	1
Letter of Information and Consent Form - September 27th, 2018	Written Consent/Assent	27/Sep/2018	3
The Foot & Ankle Disability Index (FADI) Score	Online Survey	30/Jun/1999	1

No deviations from, or changes to, the protocol or WREM application should be initiated without prior written approval of an appropriate amendment from Western HSREB, except when necessary to eliminate immediate hazard(s) to study participants or when the change(s) involves only administrative or logistical aspects of the trial.

REB members involved in the research project do not participate in the review, discussion or decision.

The Western University HSREB operates in compliance with, and is constituted in accordance with, the requirements of the TriCouncil Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2); the International Conference on Harmonisation Good Clinical Practice Consolidated Guideline (ICH GCP); Part C, Division 5 of the Food and Drug Regulations; Part 4 of the Natural Health Products Regulations; Part 3 of the Medical Devices Regulations and the provisions of the Ontario Personal Health Information Protection Act (PHIPA 2004) and its applicable regulations. The HSREB is registered with the U.S. Department of Health & Human Services under the IRB registration number IRB 00000940.

Please do not hesitate to contact us if you have any questions.

Sincerely,

Nicola Geoghegan-Morphet, Ethics Officer on behalf of Dr. Joseph Gilbert, HSREB Chair

Note: This correspondence includes an electronic signature (validation and approval via an online system that is compliant with all regulations).

Appendix B: Letter of Information and Consent



Letter of Information

Study Title:

The Feasibility of Gathering Patient-Reported Outcome Measures on Individuals with Acute Ankle Sprains in a Busy Clinic Environment

Study Investigators:

Jim Dickey	BSc, MSc, PhD	Principal Investigator	[REDACTED]
Greg Alcock	FCAMPT, MScPT, BHScPT, BA Hons PE	Co-Investigator	[REDACTED]
Ryan Reeson	BA	Student Investigator	[REDACTED]

Introduction:

Ankle sprains are the most frequently occurring sport injury and the traditional approach to treating them commonly leads to less than ideal outcomes. An acute ankle sprain can progress into a chronic injury if it is not managed appropriately. The transition into a chronic injury may lead to a lifetime of pain, a decrease in functionality, and a reduction in one's quality of life. Consequently, this progression further produces a negative impact as it can result in a financial burden to the healthcare system due to unnecessary healthcare dollars being spent on a preventable issue. Therefore, it is evident that there is room for improvement in the traditional management model for acute ankle sprains.

This study intends to start the process of forming a new model of care for acute ankle sprains; one that focuses on clinicians combining their clinical judgment with scores from outcome measures while decreasing their reliance on medical imaging. The hope is that this would give clinicians the ability to make an informed decision with regards to the appropriate course of action in a more timely fashion, ensuring the patient gets the proper care while also minimizing unnecessary expenditures on medical imaging. Ultimately, the hope is that this will reduce the number of individuals who experience chronic ankle instability and post-traumatic osteoarthritis following an acute ankle sprain. This can have a positive influence on patients' quality of life, while also saving significant amounts of healthcare dollars.

Initials: _____

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Invitation to Participate:

You are being invited to participate in this research study because you have experienced an ankle sprain. This study will explore the relationships between three self-report outcome measures while monitoring acute ankle sprains over 6 weeks.

Purpose of the Letter:

The purpose of this letter is to provide you with all the information you need to know in order to make an informed decision regarding participation in this research study.

Purpose of the Study:

The purpose of this study is to examine how the scores of the Foot and Ankle Ability Measure (FAAM), the Foot and Ankle Disability Index (FADI), and the Lower Extremity Functional Score (LEFS) change over a 6-week period following an acute ankle sprain. The LEFS is collected as part of the standard of care for acute ankle sprains while the FAAM and FADI outcome measure scores will be collected for study purposes only.

Inclusion Criteria:

You are eligible to be included in this study if you are coming through Fowler Kennedy Sports Medicine Clinic, are 16 years of age or older, and have sustained an acute ankle sprain that would be deemed appropriate for conservative management (i.e., physiotherapy).

Exclusion Criteria:

You will be excluded from participating in this study if you:

- Are under 16 years of age
- Have sustained any other lower extremity injury that would alter self-report scores (i.e., recent knee surgery)
- Have had a previous foot/ankle surgery
- Are unable to read and understand the English approved informed Consent Form (written and oral)
- Have any other systemic diseases/neuromuscular diseases that would affect outcome scores
- Are unable to have their physiotherapy at Fowler Kennedy Sports Medicine Clinic 3M Site

Study Procedures:

As part of your participation in this study, you will be required to fill out two self-report outcome measures that are designed to assess physical functioning and range from 26-31 scaled questions (i.e., the FAAM and the FADI). These two outcome measures are expected to take approximately 5 minutes to complete and you will be completing them

Initials: _____

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during your standard of care visit. You will be seen on a weekly basis for a 6-week period and the outcome measures will be collected during each of your visits. In addition to collecting your outcome measure scores, we will also be collecting some personal health information and personal identifiers during your first visit to Fowler Kennedy Sport Medicine Clinic.

Personal Benefits to Participation:

There are no direct benefits to participating in this study.

Potential Risks, Harms and Inconveniences:

There is a risk of a privacy breach as you will be providing us with personal health information and personal identifiers. The inconvenience associated with this study involves the time it takes to complete the self-report outcome measures, which will be collected via phiDB, a proprietary web application for orthopaedic research. It is expected that these will take approximately 5 minutes to complete per session, with 6 sessions to be completed throughout the study. In total, you can expect to commit 30 minutes to this study. This will, however, add no additional time to your visit as this can be completed while you are getting ice or other modalities during your stay at the clinic.

Compensation:

No compensation will be provided for participating in this study.

Voluntary Participation:

Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions, or withdraw from the study at any time. This will have no effect on your future care at the Fowler Kennedy Sports Medicine Clinic. If you withdraw from this study before its completion, you have the option to decide if you would like to withdraw your study data as well.

Confidentiality:

Your research records will be stored in a secure office in Fowler Kennedy Sports Medicine Clinic. In order to protect your confidentiality, a unique code will be used to identify you instead of any personal health identifiers. Only the principal investigator, the co-investigator, and the student investigator will have access to this code. Your contact information will also be securely kept allowing for the arrangement of follow-up visits. If the results of this study are published, your name will not be used and no information that discloses your identity will be released or published.

The data will be stored on phiDB, a proprietary web application for orthopaedic research used by the London Ontario company, Ortech Data Centre Inc. The identifiable information that you provide us will be stored in their database which is privacy compliant and encrypted. The Letters of Information and Consent Forms will be stored

Initials: _____

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in a locked filing cabinet in the office of the co-investigator in Fowler Kennedy Sport Medicine Clinic.

Contact Persons:

If you have any questions or concerns, please feel free to contact:

Student Investigator: Ryan Reeson, [REDACTED]

Co-Investigator: Greg Alcock, [REDACTED]

Principal Investigator: Jim Dickey [REDACTED]

This letter is yours to keep for future reference.

Initials: _____

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Consent Form

Study Title: The Feasibility of Gathering Patient-Reported Outcome Measures on Individuals with Acute Ankle Sprains in a Busy Clinic Environment

Principal Investigator: Jim Dickey

Co-Investigator: Greg Alcock

Student Investigator: Ryan Reeson

I, _____, have read the letter of information, have had the nature of the study explained to me and I agree to participate. All questions have been answered to my satisfaction.

Signature of Participant

Date

I, _____, the study data collector am responsible for obtaining participant consent. I verify that I have explained to the above-mentioned individual the nature of the study and all that comes with participation. I have informed the individual that participation is voluntary and that they may withdraw from the study at any time. I verify that all information obtained through this study will be kept confidential.

Signature of Person Obtaining
Informed Consent

Date

Initials: _____

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Foot and Ankle Ability Measure (FAAM)
Activities of Daily Living Subscale
Page 2

Because of your foot and ankle how much difficulty do you have with:

	No Difficulty at all	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Home responsibilities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Activities of daily living	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Personal care	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Light to moderate work (standing, walking)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heavy work (push/pulling, climbing, carrying)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Recreational activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

How would you rate your current level of function during your usual activities of daily living from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities.

___ . 0 %

**Foot and Ankle Ability Measure (FAAM)
Sports Subscale**

Because of your foot and ankle how much difficulty do you have with:

	No Difficulty at all	Slight Difficulty	Moderate Difficulty	Extreme Difficulty	Unable to do	N/A
Running	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Jumping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Landing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Starting and stopping quickly	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cutting/lateral Movements	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ability to perform Activity with your Normal technique	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Ability to participate In your desired sport As long as you like	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

How would you rate your current level of function during your sports related activities from 0 to 100 with 100 being your level of function prior to your foot or ankle problem and 0 being the inability to perform any of your usual daily activities?

____ . 0%

Overall, how would you rate your current level of function?

☐ Normal ☐ Nearly Normal ☐ Abnormal ☐ Severely Abnormal

Martin, R; Irrgang, J; Burdett, R; Conti, S; VanSwearingen, J: Evidence of Validity for the Foot and Ankle Ability Measure. Foot and Ankle International. Vol.26, No.11: 968-983, 2005.

Appendix D: Foot and Ankle Disability Index (FADI)



The Foot and Ankle Disability Index (FADI) Score and Sports Module

Patient Name: _____ Date: _____

Please answer every question with one response that most closely describes your condition within the past week by marking the appropriate number in the box. If the activity in question is limited by something other than your foot or ankle, mark N/A.

- 0 Unable to do 2 Moderate difficulty 4 No difficulty
1 Extreme difficulty 3 Slight difficulty

Standing		Walking up hills	
Walking on even ground		Walking down hills	
Walking on even ground without shoes		Going up stairs	
Walking on uneven ground		Going down stairs	
Stepping up and down curves		Squatting	
Sleeping		Coming up to your toes	
Walking initially		Walking 5 minutes or less	
Walking approximately 10 minutes		Walking 15 minutes or greater	
Home responsibilities		Activities of Daily Living	
Personal Care		Light to moderate work (standing, walking)	
Heavy work (push/pulling, climbing, carrying)		Recreational activities	

Sports Module:

Running		Jumping	
Landing		Squatting and stopping quickly	
Cutting, lateral movements		Low-impact activities	
Ability to perform activity with your normal technique		Ability to participate in your desired sports as long as you would like	

Pain related to the foot and ankle:

- 0 Unbearable 2 Moderate Pain 4 No Pain
1 Severe Pain 3 Mild Pain

General level of pain		Pain at rest	
Pain during your normal activity		Pain first thing in the morning	

Office Use Only: Score: ____/136 points (FADI 104 points & SPORTS 32 points; No Disability 136)
 Number of PT Sessions: ____ Gender: M F Age: ____
 ICD-9 Code: PT Initials:

Appendix E: Lower Extremity Functional Scale (LEFS)

The Lower Extremity Functional Scale

We are interested in knowing whether you are having any difficulty at all with the activities listed below **because of your lower limb problem** for which you are currently seeking attention. Please provide an answer for **each** activity.

Today, **do you or would you** have any difficulty at all with:

	Activities	Extreme Difficulty or Unable to Perform Activity	Quite a Bit of Difficulty	Moderate Difficulty	A Little Bit of Difficulty	No Difficulty
1	Any of your usual work, housework, or school activities.	0	1	2	3	4
2	Your usual hobbies, re creational or sporting activities.	0	1	2	3	4
3	Getting into or out of the bath.	0	1	2	3	4
4	Walking between rooms.	0	1	2	3	4
5	Putting on your shoes or socks.	0	1	2	3	4
6	Squatting.	0	1	2	3	4
7	Lifting an object, like a bag of groceries from the floor.	0	1	2	3	4
8	Performing light activities around your home.	0	1	2	3	4
9	Performing heavy activities around your home.	0	1	2	3	4
10	Getting into or out of a car.	0	1	2	3	4
11	Walking 2 blocks.	0	1	2	3	4
12	Walking a mile.	0	1	2	3	4
13	Going up or down 10 stairs (about 1 flight of stairs).	0	1	2	3	4
14	Standing for 1 hour.	0	1	2	3	4
15	Sitting for 1 hour.	0	1	2	3	4
16	Running on even ground.	0	1	2	3	4
17	Running on uneven ground.	0	1	2	3	4
18	Making sharp turns while running fast.	0	1	2	3	4
19	Hopping.	0	1	2	3	4
20	Rolling over in bed.	0	1	2	3	4
Column Totals:						

Minimum Level of Detectable Change (90% Confidence): 9 points SCORE: ____ / 80 (fill in the blank with the sum of your responses)

Source: Binkley et al (1999): The Lower Extremity Functional Scale (LEFS): Scale development, measurement properties, and clinical application. Physical Therapy. 79:371-383.

Curriculum Vitae

Name: Ryan Reeson

**Post-secondary
Education and
Degrees:** Western University
London, Ontario, Canada
2013-2017 B.A.

Western University
London, Ontario, Canada
2017-2019 M.Sc.

**Honours and
Awards:** Western Graduate Research Scholarship
2017-2019

Western Scholarship of Excellence
Valued at \$2000
2013

**Related Work
Experience** Teaching Assistant
The University of Western Ontario
2017-2019

Summer Research Student – Orthopaedics
Toronto Western Hospital – UHN
2015, 2017

Presentations:

Oral Presentation: The Feasibility of Gathering Patient-Reported Outcome Measures on Individuals with Acute Ankle Sprains in a Busy Clinic Environment

Authors: R.H. Reeson, G.K. Alcock, J.P. Dickey

Health and Rehabilitation Sciences Graduate Research Conference, Western University, February 27th, 2019

Oral Presentation: The Feasibility of Gathering Patient-Reported Outcome Measures on Individuals with Acute Ankle Sprains in a Busy Clinic Environment

Authors: R.H. Reeson, G.K. Alcock, J.P. Dickey, K. Willits

Fowler Kennedy Sports Medicine Symposium, London ON, October 19th, 2018